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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/683,830	10/10/2003	Golam Faruque Khan	AA605M2	2986

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EXAMINER

BARHAM, BETHANY P

ART UNIT	PAPER NUMBER
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1615

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05/12/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/683,830	Applicant(s) KHAN, GOLAM FARUQUE	
	Examiner BETHANY BARHAM	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2006 and 10 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-7,9,13-16 and 18-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-7,9,13-16 and 18-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) ☒ Notice of References Cited (PTO-892) | 4) ☐ Interview Summary (PTO-413) |
| 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) ☒ Information Disclosure Statement(s) (PTO/SB/08) | 5) ☐ Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/13/07</u> . | 6) ☐ Other: _____ |

DETAILED ACTION

Summary

Receipt of IDS filed on 11/13/07 is acknowledged. Receipt of Applicant's Responses and claim amendments filed on 11/3/06, 8/10/07 and 5/1/08 are acknowledged. Claims 1, 3-7, 9, 13-16 and 18-20 are pending and rejected.

Request for information under 37 C.F.R. 1.105

Again Applicant and the assignee of this application are required under 37 CFR 1.105 to provide the following information that the examiner has determined is reasonably necessary to the examination of this application. The information is required to extend the domain of search for prior art. Limited amounts of art related to the claimed subject matter are available within the Office, and are generally found in class 424 and subclasses 70.27, respectively, which describes cationic surfactant containing compositions. Specifically Applicant needs to provide all information available from Dow Corning Toray to the specific embodied amidomethicones of DC2-8500 or BY16-906.

Response to previous requests:

The Response to previous 105 requests have also been received and are acknowledged and the Applicant states that other keywords include dimethicone, dimethylpolysiloxane, etc for amidomethicones. The Applicant's argue that '418 does not teach the claimed dimethicone or "amidomethicone", however the Examiner

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respectfully points out that Applicant states (pg. 2 of 5/1/08 response) section (b) “tradenames for the amodimethicone of interest are DC2-8500 and BY16-906”, while (c) states “amidomethicone copolyol”. Thus it would appear that the terms dimethicone, amodimethicones and amidomethicones are interchangeable.

NEW REJECTIONS

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

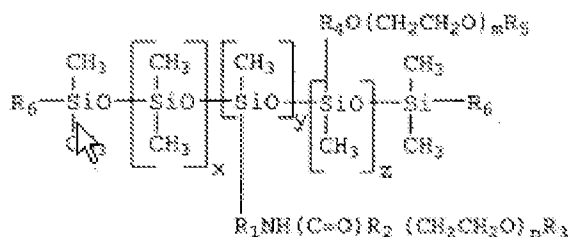
Claims 1, 3-7, 9, 13-16 and 18-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for specific amidomethicone (BY16-906 or DC2-8500), does not reasonably provide enablement for any amidomethicone of the formula in claims 1, 18 or 19 and further one cannot purchase the polymer in the United States. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Based on the instant disclosure, it is the examiner's position that Applicants do not describe this invention in such a manner that would enable one of ordinary skill in the art to practice this invention with any amidomethicone of claims 1, 18 or 19. This is a scope of enablement rejection.

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Enablement is considered in view of the Wands factors (MPEP 2164.01 (a)).

These include: (1) breadth of the claims; (2) nature of the invention; (3) state of the prior art; (4) amount of direction provided by the inventor; (5) the level of predictability in the art; (6) the existence of working examples; (7) quantity of experimentation needed to make or use the invention based on the content of the disclosure; and (8) relative skill in the art. All of the factors have been considered with regard to the claim, with the most relevant factors discussed below:

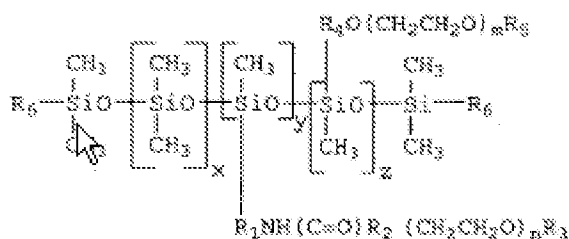
The breadth of claims: The instant claim 1 is directed to “a hair conditioning composition comprising by weight: (a) from about 0.01% to about 10% of a thickening polymer system selected from the group consisting of a cationic thickening polymer, a nonionic thickening polymer, and mixtures thereof; (b) from about 0.05% to about 10% of a cationic surfactant system wherein the cationic surfactant system is a saturated mono-alkyl trimethyl ammonium salt, wherein the alkyl group has 12 to 28 carbon atoms, and (c) from about 0.1% to about 20% of a silicone compound wherein the silicone compound is a hydrophobically modified amidomethicone copolyol having a formula



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wherein R1, R2, R4 are C1-C3 alkyl, R3 is an alkyl group having 8-22 carbon atoms; R5 is H or C1-C3 alkyl; R6 is OH or CH3; n is an integer of 1-10; m is an integer of 2-20; n+m=3-30; x is an integer from 200 to 500; y is an integer from 5 to 40; and z is 0 or an integer from 1 to 30; (d) an aqueous carrier; wherein the composition is transparent or translucent and further wherein the composition is substantially free of a water-insoluble high melting point oily compound and an anionic compound.” It is the examiner’s position that this claim is not supported by the instant specification, and that the scope supported by the specification includes only the BY16-906 and DC2-8500 amidomethicones, of which the structure is not disclosed.

The nature of the invention: The instant invention is directed to a “a hair conditioning composition comprising... (c) from about 0.1% to about 20% of a silicone compound wherein the silicone compound is a hydrophobically modified amidomethicone copolyol having a formula



wherein R1, R2, R4 are C1-C3 alkyl, R3 is an alkyl group having 8-22 carbon atoms; R5 is H or C1-C3 alkyl; R6 is OH or CH3; n is an integer of 1-10; m is an integer of 2-20; n+m=3-30; x is an integer from 200 to 500; y is an integer from 5 to 40; and z is 0 or an integer from 1 to 30...”

The state of the prior art: As set forth in WO 02/22085 B1 ('085), specific amino silicone polyether compounds are taught, but none of p, q, x, y, and z are 0, but are integers (such as BY16-907). '085 specifically teaches that z cannot be equal to 0. With a broad general disclosure, Applicants have not provided a basis for how their invention would specifically work any amidomethicone or an amidomethicone where $z=0$ as instant claimed. Applicant's state that Dow Corning BY16-906 or DC2-8500 are within the formula instant claimed but Dow Corning does not show structures and tradenames do not mean anything as they change over time. Given the instant disclosure, one of ordinary skill in the art would have to resort to trial and error experimentation in order to practice the invention commensurate in scope with the claims.

The amount of direction provided by the inventor: There is nothing in the specification that would indicate that the current invention is capable of working with any amidomethicone of the formula in claim 1. Guidance for preparing a composition with any amidomethicone of formula in claim 1 is not provided and the polymers cannot be purchased in the United States. As a result, one of ordinary skill in the art would have to revert to trial and error experimentation in order to practice the invention commensurate in scope with the instant claim set. With respect to the instant composition, there is a substantial gap between a composition comprising the amidomethicone disclosed in Examples (which have no structure provided) and

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amidomethicone of formula in instant claim 1. Consequently, a burdensome amount of research would be required by one of ordinary skill in the art to bridge this gap.

The presence or absence of working examples: Guidance for preparing amidomethicones BY16-906 and DC2-8500 is not provided nor is any structure associated with the MSDS and they cannot be purchased in the United States. There are no examples provided of any other amidomethicones, thus the scope of the entire claimed formula of amidomethicone is not supported.

The quantity of experimentation: In the instant case, there is a substantial gap between a composition comprising specific amidomethicones and one comprising any amidomethicone of formula instant claims 1, 18 or 19, the specification is not supportive of the entire instant claimed any other amidomethicone other BY16-906 and DC2-8500 listed above which do not have a structure disclosed. Consequently, a burdensome amount of research would be required by one of ordinary skill in the art to bridge this gap. In order to utilize the invention as claimed, the skilled artisan would be presented with an unpredictable amount of experimentation. The instant disclosure is broad and generic. It is not clear what specific embodiments would be required in order for one of ordinary skill in the art at the time the invention was made to practice the instant invention commensurate in scope with the claims.

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The relative skill of those in the art: the skill of one of ordinary skill in the art is very high, e.g., Ph.D. and M.D. level technology.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1, 3-7, 9, 13-16 and 18-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant's have not shown how to make and use an Amodimethicone of claim 1. Applicant's have supplied a tradename "BY 16-906" or "DC2-8500" which does not mean anything in respect to the claims as tradenames change over time.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

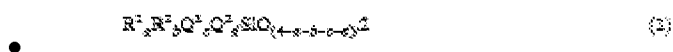
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1, 3-7, 9, 13-16, and 18-20 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,843,418 ('418) in view of US 6,086,663 ('663).

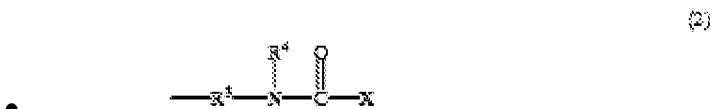
- '418 disclose a rinse off hair care compositions comprising the following: (1) from about 0.1% to about 10% by weight of a nonionic thickening polymer (column 4, lines 1- 19, abstract, and Claim 1), (2) from about 0.05% to about 1% by weight of an essential mono-long chain, tri-short chain quaternary ammonium surfactant (column 4, lines 45-51 and column 5, lines 48-60, abstract, and Claim 1), (3) an aqueous carrier, such as water (See Example 1, column 28, line 19-48). Like the instant composition, the hair care formulation advanced by '418 is substantially free of fatty alcohol materials, such as stearyl alcohol, and can be substantially free of anionic compounds (column 11, line 57 -column 12, line 2 and Example 1). The composition advanced by '418 can further comprise at least about 0.1% of a water-soluble silicone compound (Claim 25, column 14, line 27 - column 16, line 53, and column 21, line 37 - column 22, line 56). Specific types of silicone materials useful in the invention set forth by '418 include amodimethicone (column 14; lines 26-43) (meeting the limitations of claims 1a-b, 1d, 14, 16, 18a-b, 18d and 19a-b, 19d).
- According to '418, the composition can comprise a guar gum polymer and the cationic surfactant can be a formula (IV) mono-alkyl trimethyl ammonium salt having a chain from 14 to 22 carbon atoms (col. 5, lines 48-60, line 27) (meeting the limitations of claims 1b, 4-7 and 20).

- Humectants, such as polyethylene glycol, may also be included in the composition in amounts of 0.4-3% (column 10, lines 4-5 and 23-24) (meeting the limitations of claim 9 and 13).
- It is the examiner's position that, inherently, the composition advanced by '418 is transparent and has a viscosity from about 2,000 to about 50,000mPa/s. Since the essential elements of the '418 composition are identical to the instant compositions (that is, (1) from about 0.1% to about 10% by weight of a nonionic thickening polymer, (2) from about 0.1% to about 10% by weight of an unsaturated quaternary ammonium surfactant, and (3) an aqueous carrier, such as water), the composition would inherently have the same physiochemical properties as the compositions set forth in the instant application (meeting the limitations of claims 3 and 15).
- '418 does not teach amidomethicones of instant claims 1c, 18c, and 19c, but does teach an amino modified silicone.
- '663 teaches various amidepolyether modified polysiloxanes and amino-modified polysiloxanes (i.e. amidomethicones and amodimethicones) have excellent surface feel, stability, etc and exhibits excellent blending with cosmetics (col. 2, lines 29-70 and formula (1-2) and (4-5)). Specifically an amidepolyether modified polysiloxanes taught is in formula 1:

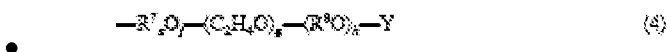


Q1 is formula 2:

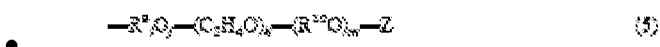
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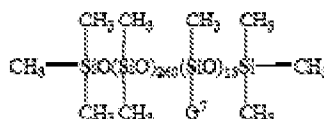
X is formula 4



Q2 is formula 5:



- Wherein R¹ is OH or CH₃, R² is CH₃, R³=2-3, R⁴=H, R⁷=2-3, f is 0, g= a positive integer of at least 1, h is 0, Y=H, i=1, j=1, R⁹ is 2-3, k is a positive integer of greater than 1, m=0 and Z=H (overlaps with the instant claimed amidomethicone copolyol).
- Further, examples teach a starting material (1) amidepolyether-modified



polysiloxane (col. 6, lines 34-42)



(that in reads on the instant claimed structure wherein the instant claimed

structure in instant claim 1 has Z=0, R¹= C₃ alkyl, R²= CH₂, R³=C₁₂H₂₅, n=5,X=260, Y=13, R⁶=CH₃).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine '418 in view of '663. One of ordinary skill in the art would know how to substitute an amino modified polysiloxane of '418 or '663 with an amidepolyether modified polysiloxane of '663 for another. Such a substitution of the amodimethicone of

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'418 for the amidomethicone of '663 is within the purview of the skilled artisan yielding predictable results.

Claims 1, 3-7, 9, 13-16, and 18-20 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,843,418 ('418) in view of the Dow Corning Toray BY16-906 polymer (a commercially available product, see MSDS and instant specification pg. 13, lines 10-11).

- '418 disclose a rinse off hair care compositions comprising the following: (1) from about 0.1% to about 10% by weight of a nonionic thickening polymer (column 4, lines 1- 19, abstract, and Claim 1), (2) from about 0.05% to about 1% by weight of an essential mono-long chain, tri-short chain quaternary ammonium surfactant (column 4, lines 45-51 and column 5, lines 48-60, abstract, and Claim 1), (3) an aqueous carrier, such as water (See Example 1, column 28, line 19-48). Like the instant composition, the hair care formulation advanced by '418 is substantially free of fatty alcohol materials, such as stearyl alcohol, and can be substantially free of anionic compounds (column 11, line 57 -column 12, line 2 and Example 1). The composition advanced by '418 can further comprise at least about 0.1% of a water-soluble silicone compound (Claim 25, column 14, line 27 - column 16, line 53, and column 21, line 37 - column 22, line 56). Specific types of silicone materials useful in the invention set forth by '418 include amodimethicone (column 14; lines 26-43) (meeting the limitations of claims 1a-b, 1d, 14, 16, 18a-b, 18d and 19a-b, 19d).

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- According to '418, the composition can comprise a guar gum polymer and the cationic surfactant can be a formula (IV) mono-alkyl trimethyl ammonium salt having a chain from 14 to 22 carbon atoms (col. 5, lines 48-60, line 27) (meeting the limitations of claims 1b, 4-7 and 20).
- Humectants, such as polyethylene glycol, may also be included in the composition in amounts of 0.4-3% (column 10, lines 4-5 and 23-24) (meeting the limitations of claim 9 and 13).
- It is the examiner's position that, inherently, the composition advanced by '418 is transparent and has a viscosity from about 2,000 to about 50,000mPa/s. Since the essential elements of the '418 composition are identical to the instant compositions (that is, (1) from about 0.1% to about 10% by weight of a nonionic thickening polymer, (2) from about 0.1% to about 10% by weight of an unsaturated quaternary ammonium surfactant, and (3) an aqueous carrier, such as water), the composition would inherently have the same physiochemical properties as the compositions set forth in the instant application (meeting the limitations of claims 3 and 15).
- '418 does not teach amidomethicones of instant claims 1c, 18c, and 19c, but does teach an amino modified silicone.
- Dow Corning Toray produces a commercially available BY16-906 (instant specification pg. 13, lines 10-11 and MSDS from Dow Corning Toray).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine '418 in view of the Dow Corning Toray polymer. One of ordinary

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skill in the art would know how to substitute one dimethicone for another. Such a substitution of the amodimethicone of '418 for the amidomethicone of Dow Corning Toray is within the purview of the skilled artisan yielding predictable results.

Response to Arguments

Applicant's arguments with respect to claims 1, 3-7, 9, 13-16, and 18-20 have been considered but are moot in view of the new grounds of rejection necessitated by applicants' amendments. Applicant argues that the term "saturated" has been added to the amended claims and that "saturated" is implicitly supported by the recited term "mono-alkyl" which is well known in the art to define a saturated aliphatic group' (response pg. 9, 2nd paragraph) and then further states that the prior art '418 does not teach saturated mono-alkyl trimethyl ammonium salts (response pg. 10, 1st paragraph). The Examiner respectfully disagrees as the prior art discloses a specific embodiment that includes about 0.05% to about 1% by weight of an essential ingredient of a mono-long chain (C14-C22), tri-short chain (C1-C6) quaternary ammonium surfactant (column 4, lines 45-51 and column 5, lines 48-60) and by Applicant's own admission a "mono-alkyl" is saturated. The presence of other unsaturated cationic surfactants in the prior art is not a teaching away as the instant claims contain the open "comprising" language.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bethany Barham whose telephone number is (571)-272-6175. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Bethany Barham
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/MP WOODWARD/
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